UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel. JOHN A. WOOD, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN and the DISTRICT OF COLUMBIA, Plaintiffs, v. ALLERGAN, INC. and ALLERGAN plc, Defendants.	Civil Action No. 10 Civ. 5645 (JMF) **ORAL ARGUMENT REQUESTED**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS RELATOR'S THIRD AMENDED COMPLAINT

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Allergan, Inc. ("Allergan") and Allergan plc[1] respectfully submit this memorandum of law in support of their Motion to Dismiss the Third Amended Complaint ("TAC") of Plaintiff John A. Wood ("Relator") pursuant to Rules 8, 9(b), 12(b)(1), 12(b)(2), and 12(b)(6) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

By law, pharmaceutical companies such as Allergan may distribute product samples for promotional purposes. The Prescription Drug Marketing Act of 1987 ("PDMA"), 21 U.S.C. § 353 *et seq*., neither caps the number of such samples nor precludes companies from providing samples to persuade physicians to prescribe particular drugs. To the contrary, the Act expressly sanctions samples "intended to promote the sale of the drug," so long as the pharmaceutical company, among other measures, maintains specified records and so long as no one sells, purchases, or trades the samples (or offers to do so). 21 U.S.C. § 353(c)(1), (d). And, under the PDMA, physicians may ask companies for drug samples (in writing) by specifying the "identity of the drug"—and the "quantity" that they want. *Id.* § 353(d)(2)(B).

Nowhere does the PDMA suggest that sampling (even in bulk) runs afoul of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). This is unsurprising. As the Department of Health and Human Services, Office of Inspector General ("OIG") has acknowledged, product samples have ***no monetary value to physicians*** unless the physicians sell them or bill for them.

Relator nevertheless insists that Allergan violated federal and state anti-kickback statutes and, as a result, federal and state false claims acts when it provided samples to physicians (both in individual deliveries and as part of customer care kits). Critically, Relator does ***not*** allege that

[1] This Court lacks personal jurisdiction over Allergan plc, and the TAC should be dismissed as to that entity pursuant to Rule 12(b)(2). *See* Part VI, *infra*. If this Court does not dismiss on that basis, Allergan plc joins the remainder of the arguments set forth in this Motion to Dismiss. *Cf.* Fed. R. Civ. P. 12(b) ("No defense or objection is waived by joining it with one or more other defenses or objections . . . or in a motion.").

Allergan encouraged physicians to sell or bill for its samples. Rather, his novel theory is that the ***volume*** of the samples and the ***packaging*** of those samples (in care kits that, he concedes, were of "nominal" value) converted permissible samples into impermissible remuneration.

But, as OIG has recognized, drug sampling—the core of Relator's case—is not inherently remunerative. Nor are the other alleged inducements that provided, at most, some value to physicians' patients (as opposed to the physicians themselves). Absent some value to the physician, the samples, kits, and other alleged inducements cannot constitute remuneration under the anti-kickback laws—and absent remuneration, Relator's claims fail because there are no kickbacks that render any certifications false (or cause any false claims) under the federal False Claims Act ("FCA") and state analogues. A holding to the contrary would appear to run counter to ***all*** past FCA cases based on sampling, which involved claims that physicians sold or billed for samples (or were encouraged to do so). Further, any such holding would sow significant confusion about how much sampling is "too much" (given that the PDMA sets no cap).

Regardless, even if Relator had alleged a viable theory of remuneration, his claims against Allergan cannot survive a motion to dismiss under Federal Rules of Civil Procedure 8, 9(b), 12(b)(1), 12(b)(2), and 12(b)(6) for the following independent reasons:

First, as a threshold matter, the FCA's so-called "first-to-file bar," 31 U.S.C. § 3730(b)(5), requires dismissal of Relator's TAC. When he filed his original complaint, two other "related" suits were "pending." Even though those claims are no longer pending—and Relator has amended his complaint—the appropriate procedure in such situations is to dismiss the operative complaint so as to effectuate the purpose of the FCA's bar.

Second, because those two earlier, related suits were served on the U.S. Attorney General, they constituted public disclosures of the substance of Relator's allegations here, and

Relator is not an "original source." 31 U.S.C. § 3730(e)(4)(A). Thus, the FCA's public disclosure bar strips this Court of jurisdiction to hear Relator's suit.

Third, the bulk of Relator's claims hinge on allegedly false certifications purportedly made by physicians and pharmacists. But the Supreme Court's recent decision in *United Health Services, Inc. v. United States ex rel. Escobar* forecloses his theory of falsity. Indeed, Relator fails to plead any representation by a physician or a pharmacist relating to Allergan's products that was itself false or fraudulent or was rendered misleading by omitted information.

Fourth, the TAC falls far short of meeting Rule 9(b)'s particularity requirements. Indeed, the TAC does not plead the requisite details of ***any*** false claims submitted to federal or state government health care programs. Although Relator alleges that a few doctors received samples of two Allergan drugs and thereafter wrote prescriptions that Medicare reimbursed, he fails to tie these assertions to: (a) any specific speaker who knowingly made a false statement or omitted material information; (b) any specific false certifications or records; (c) any element of the kickback scheme he alleges; or (d) any government health program other than Medicare.

Fifth, this Court lacks personal jurisdiction over Allergan plc.

Sixth, the applicable federal statute of limitation, and similar state statutes, require dismissal of Relator's claims to the extent they pertain to claims submitted before May 23, 2010.

Seventh, Relator's state claims suffer from several legal flaws that require dismissal.

And, ***eighth***, Relator fails to state a retaliation claim under the FCA. Although he alleges that he reported to Allergan personnel a purportedly improper sampling scheme, his reports do not constitute protected activity under section 3730(h).

For these reasons, among others, the TAC must fail. Further, as explained below, Relator cannot cure the TAC's deficiencies. This Court should dismiss the TAC with prejudice.

RELEVANT BACKGROUND

Allergan, Inc. Allergan, a "pioneer in the development of prescription eye care products," manufactures, markets, promotes, and sells prescription drugs and over-the-counter drops. TAC ¶ 22. Allergan promotes its products to, among others, ophthalmologists and optometrists. *See, e.g.*, *id.* ¶ 45. Like many pharmaceutical companies, Allergan has provided samples of certain drugs to physicians for promotional purposes. *See id.* ¶¶ 130–131. As the TAC alleges, Allergan documented its provision of samples to physicians. *See, e.g.*, *id.* ¶ 172.

Allergan plc. Allergan plc is an Irish holding company formed in 2013. Declaration of James C. D'Arecca ("D'Arecca Decl.") ¶¶ 5–6. Unlike its subsidiary, Allergan, Inc., Allergan plc does not manufacture, market, promote, distribute, or sell pharmaceuticals in the United States (or elsewhere, for that matter). *Id.* ¶¶ 6, 10. Allergan plc did not acquire Allergan, Inc. until March 2015—long after the activities alleged in the TAC purportedly occurred. TAC ¶ 26.

Procedural History. In July 2010, Relator filed suit, on his own behalf and on behalf of the United States, twenty-six states, and the District of Columbia, under the *qui tam* provisions of the FCA and various state laws. ECF No. 61. He filed his First Amended Complaint ("FAC") in August 2010, ECF No. 63, and his Second Amended Complaint ("SAC") in March 2012, ECF No. 27. Despite Relator's allegation that Allergan "cheated the Federal Government and . . . States into paying hundreds of millions of dollars in prescription drug claims that were not eligible for reimbursement," TAC ¶ 12, ***not one*** government intervened. *See* ECF Nos. 25, 26. This Court unsealed the SAC in March 2016. *See* ECF Nos. 24, 27. Relator's TAC, filed May 23, 2016, contains thirty-one counts: five under the FCA, and one count for each of the twenty-five remaining states and the District of Columbia. *See* ECF No. 38; TAC ¶¶ 275–473.[2]

[2] Neither the SAC nor the TAC pleads a count tied to New Hampshire law (despite the captions of those pleadings). This Court dismissed Relator's claim under Maryland law. *See* ECF No. 29, at 3.

The TAC's Allegations. Like Relator's first three complaints, the TAC alleges that Allergan offered and provided kickbacks to physicians in the form of drug samples, patient or customer care kits, custom-printed patient instruction sheets, and preprinted prescription pads. *See* TAC ¶¶ 136–166 (care kits), 167–191 (sample shipment agreements), 208–218 (prescription pads and patient instruction sheets). Relator asserts that Allergan provided product samples to certain physicians from "as early as 2003" until June 2010. *Id.* ¶¶ 31, 185. According to Relator, Allergan also packaged drug samples with other items of "nominal" value to create care kits for patients' use pre- and post-surgery. *Id.* ¶ 137 (alleging that care kits included prescription drug samples, "a sample of [Allergan's] Optive® or Refresh® artificial tears; protective sunglasses for post-surgical use; a protective eye shield; tape and gauze to construct a protective eye patch; and an over-the-counter analgesic such as Tylenol or Advil"). Relator alleges that, from 2003 through December 2008, Allergan delivered care kits for free to physicians or practices that then, in turn, distributed them for free to patients. *Id.* ¶ 136. Relator also asserts that Allergan gave practices instruction sheets intended to educate patients about the pre- and post-surgery process, as well as preprinted prescription pads. *Id.* ¶¶ 208–218.

According to Relator, physicians who received the alleged kickbacks subsequently prescribed Allergan products to beneficiaries of federal health care programs, "including Medicare, Medicaid, TRICARE, and the Veterans Administration healthcare programs, as well as state healthcare programs, including Medicaid." *Id.* ¶ 220. Relator alleges that, as a result, pharmacies submitted false claims for reimbursement, and that both those pharmacies and the prescribing physicians falsely certified compliance "with applicable laws which require express and implied certifications of compliance with conditions of payment." *Id.* ¶ 239.

LEGAL STANDARDS

Applicable Standards of Review. To survive scrutiny under Rules 8 and 12(b)(6), a plaintiff must allege facts that, if true, would "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A complaint cannot overcome a motion to dismiss if it relies on "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," *id.*, or "factual" allegations that amount to no more than legal conclusions, *Twombly*, 550 U.S. at 555.

Because the FCA "is an anti-fraud statute," a relator also must satisfy Rule 9(b)'s strict pleading standard, which requires asserting "with particularity" "the circumstances constituting fraud." *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476–77 (2d Cir. 1995) (per curiam). At a minimum, Relator must "(1) specify the statements that [he] contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *United States ex rel. Wood v. Applied Research Assocs., Inc.*, No. 07-CV-3314, 2008 WL 2566728, at *5 (S.D.N.Y. June 26, 2008), *aff'd,* 328 F. App'x 744, 747 (2d Cir. 2009). AKS allegations underlying FCA claims also must be stated with particularity. *See, e.g.*, *United States ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806, 2013 WL 1346022, at *3 (E.D.N.Y. Apr. 3, 2013) (allegations regarding "other wrongful activities that result in the submission of fraudulent claims" must satisfy Rule 9(b)).

False Claims Act. The FCA imposes treble damages and per-claim penalties on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," as well as any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C.

§ 3729(a)(1)(A)–(B).[3] Through its modern permutations, the FCA's "focus [has] remain[ed] on those who present or directly induce the submission of false or fraudulent claims." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016).

To state an FCA claim, Relator must prove that Allergan knowingly made, or caused to be made, a false or fraudulent claim to the government for payment. *See Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001). In the Second Circuit, falsity comes in two forms. A factually false claim seeks payment for goods or services that were not actually provided or rendered; a legally false claim involves a "false representation of compliance with a federal statute or regulation or a prescribed contractual term," *id.* at 696–97, or a material omission that renders misleading specific statements made about goods or services, *Escobar*, 136 S. Ct. at 2001.

Anti-Kickback Statute. Relator's theory of falsity hinges on alleged violations of the AKS and state analogues. The AKS makes it a crime to, *inter alia*, "knowingly and willfully offer[] or pay[] any remuneration . . . to induce [any] person" to prescribe a drug "for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). An AKS violation alone is insufficient to trigger FCA liability. Instead, with regard to claims submitted before March 23, 2010,[4] Relator must establish some ***falsity*** associated with each claim that he alleges was submitted to the government. *See United States ex rel. Panarello v. Kaplan Early Learning Co.*, No. 11-CV-353S, 2014 WL 1315367, at *4

[3] With regard to claims pending before June 7, 2008, the prior version of 31 U.S.C. § 3729(a)(1)(B) imposed liability on any person who "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved . . . ." *See* Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111–21 § 4(f), 123 Stat. 1617, 1625; 31 U.S.C. § 3729(a)(2) (pre-FERA).

[4] Effective March 23, 2010, the Patient Protection and Affordable Care Act ("ACA") amended the AKS to provide that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim." Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, 759 (2010). Because the ACA does not apply retroactively, the amendment is inapplicable to claims submitted before the ACA's effective date. *See United States v. TEVA Pharm. USA, Inc.*, No. 13 CIV. 3702, 2016 WL 750720, at *20 (S.D.N.Y. Feb. 22, 2016). Here, Relator alleges that Allergan stopped providing free care kits in December 2008, *see* TAC ¶ 136, and that the purported sampling scheme ended in June 2010, just after the ACA's effective date, *see id.* ¶ 185.

(W.D.N.Y. Mar. 31, 2014) (FCA liability depends on the "claim for payment" rather than the "underlying fraudulent activity or . . . the government's wrongful payment."). For claims postdating March 23, 2010, Relator must establish that the claim "result[ed] from" a violation of the AKS. 42 U.S.C. § 1320a-7b(g).[5]

ARGUMENT

I. THE FCA'S FIRST-TO-FILE BAR REQUIRES DISMISSAL OF RELATOR'S THIRD AMENDED COMPLAINT

"When a person brings an [FCA] action . . . no person other than the Government may . . . bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). This provision bars this case because two actions involving nearly identical allegations were pending at the time Relator filed suit. *See Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1978–79 (2015). Dismissing the TAC is the only way to cure this violation of the FCA's first-to-file bar and effectuate the provision's intent.[6]

For the first-to-file bar to apply, the first action must be "pending" and the second action must be "related . . . based on the facts underlying the" first action. 31 U.S.C. § 3730(b)(5). The facts underlying the actions need not be identical. *See, e.g.*, *United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111, 118 (1st Cir. 2014). Rather, the cases must simply allege the "same material elements" of fraud. *United States ex rel. Smith v. Yale-New Haven Hosp., Inc.*, 411 F. Supp. 2d 64, 75 (D. Conn. 2005) ("Every circuit to have addressed this issue has rejected an 'identical facts' test in favor of an 'essential claim' or 'same material elements'

[5] With certain exceptions (see Part VIII, *infra*), the state false claims and anti-kickback statutes that Relator invokes are materially similar to the FCA and the AKS, respectively. Thus, Relator's state-law claims must fall alongside his federal claims.

[6] The bar is intended to "prevent the filing of more *qui tam* suits once the government already has been made aware of the potential fraud," *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 517 (6th Cir. 2009), and to "discourage . . . parasitic lawsuits that merely feed off previous disclosures of fraud," *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376 (5th Cir. 2009).

standard." (alterations omitted) (quoting *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279) (10th Cir. 2004)).

A first-filed action does not bar a new claim in perpetuity. *See Carter*, 135 S. Ct. at 1978–79. But if the first-to-file bar attaches at the time when a relator filed an initial complaint, the only way to cure the defect is to dismiss the case (even if the first-filed action is no longer pending). *See United States ex rel. Carter v. Halliburton Co.*, 144 F. Supp. 3d 869, 883 (E.D. Va. 2015) ("[R]egardless of the substance of the amendments, [relator] can only cure the first-to-file bar that attached at the time he filed the initial complaint by dismissing the case.").[7]

Although neither the Second Circuit nor any district court in the Circuit appears to have addressed this issue, this Court should follow the cases requiring dismissal for several reasons:

- ***First***, the rule applied by those courts comports with the plain language of 31 U.S.C. § 3730(b)(5). *See, e.g.*, *Carter*, 144 F. Supp. 3d at 880–81 (a plaintiff "bring[s] an action" by commencing suit, ***not*** by amending a complaint, and thus the FCA's plain text directs courts to focus on the time when the relator first filed suit); *United States ex rel. Shea v. Verizon Commc'ns, Inc.*, No. 09-1050, 2015 WL 7769624, at *11 (D.D.C. Oct. 6, 2015).

- ***Second***, the Second Circuit has applied the first-to-file provision as a jurisdictional bar.[8] *United States ex rel. Pentagen Techs. Int'l, Ltd. v. CACI Int'l Inc.*, No. 97-6326, 1999 WL 55259, at *1 (2d Cir. Feb. 5, 1999) (affirming dismissal of an action under the first-to-file bar "for lack of subject-matter jurisdiction"); *see also Smith*, 411 F. Supp. 2d at 74. Whether subject-matter jurisdiction exists "depends on the state of things at the time of the

[7] *See also Shea*, 2015 WL 7769624, at *11 ("The only way to cure this particular defect is for the Court to dismiss Plaintiff's action—not merely his Complaint—so that he may file a new action . . . ."); *United States ex rel. Moore v. Pennrose Props., LLC*, No. 3:11-cv-121, 2015 WL 1358034, at *18 (S.D. Ohio Mar. 24, 2015) (dismissing action even though first-filed action was no longer pending); *United States ex rel. Branch Consultants, LLC v. Allstate Ins. Co.*, 782 F. Supp. 2d 248, 260 (E.D. La. 2011) (dismissing action against one defendant on that ground). The First Circuit and a few district courts have concluded that a supplemental pleading, rather than dismissal, can cure the jurisdictional defect resulting from a violation of the first-to-file bar. *See, e.g.*, *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 5–6 & n.2 (1st Cir. 2015); *United States v. Cephalon, Inc.*, No. 08-287, 2016 WL 398014, at *5 (E.D. Pa. Feb. 2, 2016). But even if this Court were to adopt this approach, applicable statutes of limitation still require dismissal with prejudice of nearly all of Relator's claims. *See* Part VII, *infra*.

[8] Because the first-to-file bar is jurisdictional, Allergan moves to dismiss under Rule 12(b)(1) for lack of subject-matter jurisdiction. If this Court determines that the amended bar is not jurisdictional, however, Allergan asks this Court to dismiss the TAC under Rule 12(b)(6) for failure to state a claim. *See United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 119 (D.C. Cir. 2015), *cert. denied*, 2016 WL 3461577 (U.S. June 27, 2016).

action brought." *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473 (2007). Accordingly, it "is consistent with a jurisdictional limitation to apply the first-to-file bar at the time the initial complaint is filed." *Carter*, 144 F. Supp. 3d at 881 (citing consistent Fourth, Tenth, and Ninth Circuit cases).

- ***Third***, permitting a relator to cure a first-to-file defect by amending the complaint would encourage relators to file "a skeletal complaint to secure a place in the 'jurisdictional queue . . . only to then file an amended complaint after actually" developing information to support their allegations, "thereby trump[ing] any meritorious, related actions that were filed in the meantime." *Carter*, 144 F. Supp. 3d at 882 (quoting *Branch Consultants,*782 F. Supp. 2d at 264).

When Relator filed his original complaint under seal on July 26, 2010, ECF No. 61, two actions alleging the same essential elements were pending: *United States ex rel. Caryatid, LLC v. Allergan, Inc.*, No. 10-46 (D.D.C. filed Jan. 11, 2010; dismissed Jan. 23, 2012) and *United States ex rel. Lampkin v. Johnson & Johnson, Inc.*, No. 08-5362 (D.N.J. filed Oct. 29, 2008; dismissed Dec. 14, 2012). *See* Request for Judicial Notice ("RJN") Exs. 1–5. For purposes of section 3730(b)(5), Relator's action is related to both because the relators in those cases alleged that Allergan violated the AKS by providing free patient kits, including samples, to ophthalmologists. *See* RJN Ex. 1 (*Caryatid* Compl. ¶¶ 14, 18–19 (Allergan violated the AKS by "provid[ing] ophthalmologists with free or below-market cost patient kits which included Acular LS, Pred Forte, and Zymar," as well as "eye patches and dressings, sunglasses and a carrying case labeled with Allergan's logo and/or the name and logo of the ophthalmologist.")); RJN Ex. 3 (*Lampkin* FAC ¶ 14 (Allergan violated the AKS by paying "kickbacks to doctors nationwide in the form of, *inter alia*, free surgical kits that have a greater than nominal value.")). These allegations are nearly identical to Relator's original allegations.[9] Given this overlap, Relator cannot show that his original complaint "allege[d] a different type of wrongdoing" and "gives rise to a separate recovery of actual damages by the government," as is required to demonstrate

[9] *See* ECF No. 61 (Compl. ¶¶ 3–4, 9) (alleging that Allergan violated the AKS by providing care kits to ophthalmologists containing free prescriptions of Allergan drugs); *see also* ECF No. 63 (FAC ¶¶ 3–4, 10).

that the actions are not "related." *See Smith*, 411 F. Supp. 2d at 76.

Because Relator's case is "related" to two cases pending when he filed this suit, the first-to-file bar attaches, and this action should be dismissed to dissolve the statutory bar.

II. THE FCA'S PUBLIC DISCLOSURE BAR REQUIRES DISMISSAL

The *Caryatid* and *Lampkin* complaints also constituted public disclosures that strip this Court of jurisdiction.[10] The FCA's public disclosure bar, 31 U.S.C. § 3730(e), precludes "parasitic lawsuits" brought by those who "contributed nothing to the exposure of the fraud." *United States ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 344 (S.D.N.Y. 2014). Under that provision, courts must "dismiss a *qui tam* suit . . . where the defendant was publicly accused of similar wrongdoing prior to the filing of the relator's complaint," unless the relator is an "original source." *Id*. As the Seventh Circuit has held, "[d]isclosure of information to a competent public official about an alleged false claim . . . [is a] public disclosure . . . when the disclosure is made to one who has managerial responsibility for the very claims being made." *United States v. Bank of Farmington*, 166 F.3d 853, 861 (7th Cir. 1999).[11]

The *Caryatid* and *Lampkin* relators asserted that they served their respective complaints (and statements of "all material evidence and information" they possessed) on the U.S. Attorney General and the appropriate U.S. Attorney's Offices—the public officials responsible for investigating FCA violations—in accordance with section 3730(b)(2) of the FCA. RJN Ex. 1

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[10] The public disclosure provision is still a jurisdictional barrier, even after the ACA amendments to the FCA. *See United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 103 n.4 (2d Cir. 2010) ("[t]his [public disclosure bar] provision has recently been amended to specify that in order for the ***jurisdictional bar*** to apply . . . ." (emphasis added)), *rev'd on other grounds by* 563 U.S. 401 (2011); *see also Kester*, 43 F. Supp. 3d at 345–46 ("[T]he 2010 amendment to Section 3730(e)(4)(A) did not alter the jurisdictional nature of the public disclosure bar."); *but see, e.g.*, *Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 294 (S.D.N.Y. 2013). Even if this Court holds that the bar is no longer jurisdictional for claims postdating the amendments, the Court would still lack jurisdiction over claims predating March 23, 2010, and the post-ACA bar would require dismissal of the remaining claims under Rule 12(b)(6).

[11] The circuits have split regarding whether disclosure to "a competent public official" satisfies the public disclosure bar, but the Second Circuit has not addressed this issue. For the reasons discussed here, this Court should adopt the Seventh Circuit's approach.

(*Caryatid* Compl. ¶ 6); RJN Ex. 4 (*Lampkin* FAC ¶ 9). As explained above, those two complaints alleged nearly identical misconduct to that asserted here. Thus, the FCA's public disclosure provision bars Relator's case. *See Bank of Farmington*, 166 F.3d at 861.

Relator cannot salvage his case on the basis that he is an "original source" of the information underlying the TAC's allegations. 31 U.S.C. § 3730(e)(4)(B). He does not qualify for this exception because (1) he does not allege that he "voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based" ***before*** the public disclosure, and (2) he has no knowledge that either is independent of or materially adds to the publicly disclosed allegations or transactions. 31 U.S.C. § 3730(e)(4)(B) (post-ACA statute). *Cf. United States ex rel. Bogina v. Medline Indus., Inc.*, 809 F.3d 365, 369 (7th Cir. 2016) (ACA amendments are not retroactive, but the amendment to the original source exception was "clarifying rather than . . . substantive" and therefore "is not subject to a retroactivity bar."). Therefore, this action should be dismissed.

III. RELATOR FAILS TO ALLEGE A PREDICATE AKS VIOLATION

According to Relator, Allergan provided remuneration to physicians primarily in the form of items that the physicians ultimately delivered ***to patients***: drug samples, care kits, instruction sheets, and preprinted prescription pads. *See* TAC ¶¶ 4, 32, 125. But absent some plausible allegation that anything Allergan provided was of value—and thus remunerative—***to physicians***, the TAC cannot state an AKS violation. And because Relator's theory of FCA liability depends on purported violations of the AKS, the TAC should be dismissed for failure to state a claim. *See United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 326 (S.D.N.Y. 2014).

A. As a Matter of Law, Drug Samples—Without More—Are Not Remuneration

Relator asserts that Allergan's drug samples amounted to impermissible remuneration under the AKS. But, like anything else, drug samples must have value to the recipient to

constitute remuneration. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance"), 68 Fed. Reg. 23,731, 23,737–39 (May 5, 2003) (drug samples "trigger liability" under the FCA and AKS only "if the samples have monetary value to the recipient"). As OIG has recognized, drug samples have ***no monetary value whatsoever to a physician*** unless the physician sells them or bills for them. *Id.* at 23,739; *see also id.* (recommending that pharmaceutical companies convey to physicians that "samples may not be sold or billed (thus ***vitiating any monetary value*** of the sample)" (emphasis added)).

Just as OIG has concluded that drug samples, ***without more***, are not remunerative, several courts have indicated that free procedures constitute "remuneration" under the AKS ***only*** when physicians bill for the procedures. *See, e.g.*, *United States v. Medtronic, Inc.*, No. CV 11-10790, 2016 WL 2993167, at *5 (D. Mass. May 23, 2016) (providing "what would . . . otherwise [be] innocuous" free procedures to patients was "transform[ed]" into remuneration because defendant "instructed physicians on billing Medicare for [those] procedures"); *United States ex rel. Freedman v. Suarez-Hoyos*, 781 F. Supp. 2d 1270, 1280 (M.D. Fla. 2011) (free pathology reports were remuneration because the recipient allegedly "billed Medicare" for the reports).

Here, Relator does not allege that any physician sold or billed for the Allergan drug samples (let alone that Allergan encouraged them to do so). To the contrary, Relator alleges that physicians gave the samples away for free to patients. *See, e.g.*, TAC ¶ 32 ("The physicians . . . provided the . . . free samples to Government Program Beneficiaries . . . ."). [12] Thus, the samples that Allergan allegedly provided lacked any monetary value to physicians—indeed, the value of those samples is "vitiat[ed]." OIG Guidance, 68 Fed. Reg. at 23,739.

[12] Relator also appears to allege that Allergan somehow ran afoul of the beneficiary inducement statute, 42 U.S.C. § 1320a-7a(a)(5). *See, e.g.*, TAC ¶¶ 10, 165. But Allergan is not subject to that statute. *See* OIG, *Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries* 5 (Aug. 2002), https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf ("[T]he OIG does not believe that drug manufacturers are 'providers, practitioners, or suppliers' for the limited purposes of section 1128A(a)(5) . . . .").

Relator nevertheless asserts that Allergan violated the PDMA and AKS by distributing samples to encourage physicians to prescribe Allergan drugs. TAC ¶ 92. He is wrong, as both the PDMA's text and legislative history demonstrate. *See* 21 U.S.C. § 353(c)(1) (defining "drug sample" as a unit of drug that is "intended to ***promote the sale of the drug***") (emphasis added); S. Rep. No. 100-303, at 2–3 (1988), *as reprinted in* 1988 U.S.C.C.A.N. 57, 58–59 (clarifying that a manufacturer's "providing samples of [its] prescription drugs . . . to acquaint the practitioner with the therapeutic value of the medication and thus ***encourage the written prescription of the drug***" is a "valuable medical tool" that the PDMA "is designed to retain the positive benefits of" (emphasis added)).

The PDMA's prohibition of "trading" samples does not salvage Relator's theory. Far from precluding promotional sampling, that provision was intended to restrict "[f]ree samples of prescription drugs intended for use by physicians [from] be[ing] sold or traded . . . before reaching the physician," *see* 134 Cong. Rec. S3684-01, 1988 WL 1086161 (daily ed. Mar. 31, 1988) (remarks of Senator Matsunaga, sponsor of the Senate's version of the bill), and to prevent physicians from selling or trading samples, *see* FDA Guidance, PDMA of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, 59 Fed. Reg. 11,842, 11,852–53 (Mar. 14, 1994). Here, the TAC does not allege that Allergan sold or traded samples before they reached physicians or that the physicians did so. In sum, Relator cannot plausibly plead AKS violations based on Allergan's purported sampling practices.[13]

B. Relator Fails to Allege Plausibly that Patient Care Kits, Patient Instruction Sheets, and Preprinted Prescription Pads Amounted to Remuneration

[13] Even if this Court were to disagree, the ambiguity about these regulations would undermine any allegation that Allergan ***knowingly*** caused false claims to be submitted in violation of the FCA (or that physicians ***willfully and knowingly*** violated the AKS and then falsely certified that they complied with the statute). *See Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007) ("Where . . . the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator.").

Patient Care Kits. The TAC does not plausibly allege that care kits had any independent value to physicians. *See* OIG Guidance, 68 Fed. Reg. at 23,737 ("goods or services provided by" a manufacturer must have "independent value" to the recipient to implicate the AKS); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 68 (D. Mass. 2011) (recognizing that a "free product" must have "independent value" to the recipient to violate the AKS).

As an initial matter, Relator concedes that the value of each care kit was "nominal." *See* TAC ¶ 162 (alleging that after Allergan halted distribution of care kits for free, they were made available "at a nominal cost"); *cf. id.* ¶ 153 (alleging retail value of components of care kits). And Relator also concedes that the ***contents*** of the care kits benefitted ***patients***, not physicians. *Id.* ¶ 137 (alleging that care kits contained samples, as well as sunglasses, eye shields, tape, gauze, and pain relievers). It would be illogical to argue otherwise: the samples in the kits have no monetary value to physicians (absent circumstances not alleged here), and the remaining items are not items that could confer independent value. *Cf.* OIG Advisory Opinion No. 12-20, 2012 WL 7148096, at *2 (Dec. 12, 2012) ("a free computer provided to a physician by a laboratory would have no independent value to the physician if the computer could be used only . . . to print out test results produced by the laboratory," but a "computer that the physician could use for a variety of purposes would have independent value").

Relator's sole allegation about the value of the care kits ***to physicians***—that display of "the practice or doctor's name" on the side of the kit provided "advertising and marketing" value, TAC ¶¶ 47, 137–139, 165, 168—is implausible and, in any event, undermined by the TAC. According to Relator, the care kits were valuable to physicians because they "induce[d] patients to select these physicians for their cataract surgeries." *Id.* ¶¶ 47, 165. But, as the TAC acknowledges, patients received the care kits during pre-surgery visits—that is, at a time when

the patient had ***already selected*** that practice or physician to perform surgery. *Id.* ¶ 138. Thus, by Relator's own admission, the care kits lack any viable advertising value because they were not "likely to influence [patients in their] selection of a particular provider." *Id.* ¶ 165.[14]

Notably, Relator does not allege that physicians derived value from the care kits in any other way (e.g., by using their contents or selling or billing for them). To the contrary, he alleges that the physicians "provided the free [care kits] to their patients." *Id.* ¶ 4. As such, Relator's allegations bear no resemblance to cases in which physicians received value through claims for reimbursement for free kits. *See, e.g.*, *United States ex rel. Judd v. Quest Diagnostics, Inc.*, No. 10-4914, 2014 WL 2435659, at *9 (D.N.J. May 30, 2014) (plaintiff's AKS allegations were sufficient where defendant provided "free in-office Strep Test Kits" for which recipients "could seek reimbursement directly from the government, by submitting claims . . . for reimbursement of costs of test kits that were never incurred by the providers"), *aff'd*, 638 F. App'x 162 (3d Cir. 2015). In sum, the care kits are not "remuneration" as a matter of law.

Patient Instruction Sheets and Preprinted Prescription Pads. Relator's own allegations also refute his assertion that the patient instruction sheets and prescription pads purportedly provided by Allergan were remuneration. Relator contends that the pads and sheets had some value to physicians because they often had the "physician or clinic's name and/or logo" printed on them, TAC ¶¶ 9, 209, which purportedly influenced "patients to select these physicians for their cataract surgeries," *id.* ¶¶ 47, 165. Yet, as with the care kits, Relator acknowledges that physicians provided instruction sheets outlining pre- and post-operative drug regimens and prescriptions to patients "[i]n conjunction with their cataract surgeries," *id.* ¶ 209, that is, ***after***

[14] To the extent there was any advertising "value" in displaying the name of a practice or physician to a patient that has ***already chosen a physician***, that value is nominal at most, and thus does not violate the AKS. *Cf. Miller v. Abbott Labs.*, --- F. App'x ---, 2016 WL 2799688, at *5 (6th Cir. May 12, 2016) (per curiam) (explaining that items must be valuable enough to reasonably induce the recipient).

they had already selected a physician or practice. This allegation negates the purported value of the instruction sheets to the physicians. As for the prescription pads, Relator asserts that they were "pre-printed prescriptions ***for Allergan drugs***," *id.* ¶¶ 208, 212 (emphasis added), and were not forms that could be used by physicians for other purposes. This is akin to the "free computer provided to a physician by a laboratory" that the OIG found to lack independent value to the physician so long as it "could be used only . . . to print out test results produced by the laboratory." OIG Advisory Opinion No. 12-20, 2012 WL 7148096, at *2 (Dec. 12, 2012).

For all of these reasons, the TAC fails to plead any remuneration cognizable under the AKS—and, as a result, Relator cannot plead any false claims under the FCA. The TAC should be dismissed with prejudice under Rules 8 and 12(b)(6).[15]

IV. RELATOR'S THEORY OF FALSITY AS TO PRE-AFFORDABLE CARE ACT CLAIMS FAILS AS A MATTER OF LAW

Throughout the TAC, Relator calls the claims at issue "tainted" by the alleged kickbacks, as if that label (without more) satisfies the FCA's falsity element by rendering the claims "factually false." TAC ¶ 77. It does not. Rather, Relator must show that the claims at issue are "legally false." *See, e.g.*, *United States v. TEVA Pharm. USA, Inc.*, No. 13 CIV. 3702, 2016 WL 750720, at *21 (S.D.N.Y. Feb. 22, 2016) (rejecting assertion that "claims tainted by kickbacks are somehow factually, as opposed to legally, false claims"). In the alternative, Relator is reduced to asserting that claims for reimbursement for Allergan drugs were false because unnamed physicians and pharmacies submitted unspecified certifications expressly or impliedly certifying compliance with the AKS. But this theory cannot survive scrutiny after *Escobar*.

[15] This Court should deny leave to amend as futile. In the TAC, Relator alleges that physicians gave the samples and care kits away for free to patients who had already selected their physicians. Relator cannot now amend his pleading to allege that physicians sold or billed for the samples or care kits, or provided the care kits or instruction sheets to prospective patients. *See, e.g.*, *Kant v. Columbia Univ.*, No. 08 CIV. 7476, 2010 WL 807442, at *4 (S.D.N.Y. Mar. 9, 2010) (denying leave to amend where proposed amended complaint "present[ed] new facts and allegations . . . contradictory to [plaintiff's] earlier pleadings") (collecting cases). Leave to amend also should be denied because Relator has already amended his complaint three times.

There, the Supreme Court tied theories of falsity under the FCA to common law principles. *Escobar*, 136 S. Ct. at 1999 (construing "false" and "fraudulent" under the FCA in accordance with the "well-settled meaning of th[ose] common-law terms") (quoting *Sekhar v. United States*, 133 S. Ct. 2720, 2724 (2013)). The Court held that "[w]hen . . . a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Id.*

The physician and pharmacy certifications that Relator relies on (without the requisite particularity, as explained below in Part V) in the TAC are not false or fraudulent.

Physicians' Certifications. According to Relator, physicians "must sign and submit to CMS various Provider Applications, Provider Agreements, and Claim Forms that include various certifications of compliance with applicable laws – including the AKS." TAC ¶ 78; *see also id.* ¶ 79 (citing "Medicaid Provider Application[s] [that] var[y] from state to state"). But the "standard Medicare Provider Agreement" quoted in the TAC contains forward-looking statements regarding a provider's agreement to comply, ***in the future***, with applicable laws. *See id.* ¶ 80 ("I agree to abide by the Medicare laws, regulations and program instructions . . . ."). Such statements cannot be false absent a then-existing intent not to abide by the pledge. *See United States ex rel. O'Donnell v. Countrywide Home Loans, Inc.*, 822 F.3d 650, 662 (2d Cir. 2016) (holding that breach of contractual promise can "only support a claim for fraud upon proof of fraudulent intent not to perform the promise ***at the time of contract execution***") (emphasis added). Yet Relator does not allege (let alone plausibly) that any physician signed the agreement while intending not to abide by his or her commitment.

Nor can Relator plausibly allege that any statement in the "standardized Claim Form used

for Medicare, CHAMPUS, and Medicaid" is rendered misleading ***as to Allergan drugs*** by the physicians' omission of the purported kickbacks. *Cf. Escobar*, 136 S. Ct. at 2000 (analyzing the extent to which the payment codes included by defendant in its reimbursement claims "represented that it had provided" certain treatment). Indeed, as Relator concedes, the physicians' certifications merely stated that "they are entitled to receive payment" (for the services they rendered). TAC ¶ 82. Even accepting Relator's allegations about the physicians' conduct as true, a physician's statement that he or she is entitled to payment for ***his or her services*** does not implicate the separate question of whether a pharmacy should be reimbursed for filling a prescription written by the physician. *Cf. United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 619–20 (2d Cir. 2016) (expressing skepticism about false certification theory in off-label case). And, as such, Relator fails to plead falsity based on physicians' certifications.[16]

Pharmacies' Certifications. Relator's reliance on pharmacies' purported (but also unidentified) certifications, whether express or implied, is even less availing.[17] Relator acknowledges that pharmacies certify that "***they*** [i.e., the pharmacies] are in compliance with all applicable federal and state laws." TAC ¶ 227 (emphasis added). Absent some allegation—and the TAC includes none—that the unnamed pharmacies somehow violated applicable federal and state laws themselves, the pharmacies' statements are ***literally true***—and thus cannot be false for purposes of the FCA. *See, e.g.*, *United States ex rel. Milam v. Regents of Univ. of Cal.*, 912 F. Supp. 868, 883 (D. Md. 1995) ("[A]s a matter of law . . . [FCA] liability cannot be imposed on the basis of a literally true statement."). Further, Relator concedes, as he must, that the

[16] Even assuming that a physician's AKS violation could render a certification tied to his or her services false with respect to a prescription, Relator would still have to plead that the physician ***knew*** when certifying that he or she had violated the AKS. Aside from two general, conclusory allegations to the contrary, *see* TAC ¶¶ 221, 241, the TAC does not address this issue.

[17] Relator identifies only one form that some pharmacies may have completed: Form CMS 855-S. TAC ¶ 80. Yet, as Relator acknowledges, that form is for "Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers," not prescription eye care products like those at issue here. *Id.*

"unwitting[]" pharmacies did not know of Allergan's alleged violations of the AKS. TAC ¶ 226. This eliminates the pharmacies' certifications as a basis for falsity.

Relator identifies no statements that are either false or rendered misleading by omitted information. Thus, his claims fail under Rules 8 and 12(b)(6) with regard to all claims submitted before March 23, 2010, the ACA's effective date.[18]

V. RELATOR FAILS TO PLEAD ANY FALSE CLAIM WITH PARTICULARITY

The "*sine qua non*" of an FCA violation is a false claim for payment. *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 336 (D. Conn. 2004). A relator need not plead the particulars of each allegedly false claim, but he must ***at least*** "provide . . . examples of specific false claims submitted to the government" as a result of the fraudulent scheme he has alleged. *United States v. Wells Fargo Bank, N.A.*, 972 F. Supp. 2d 593, 616 (S.D.N.Y. 2013) (Furman, J.). Any such example claims must be "***representative*** samples of the broader class of claims" if they are to "support more generalized allegations of fraud" encompassing the entire alleged scheme. *Id.* (emphasis added); *cf. United States ex rel. Corp. Compliance Assocs. v. N.Y. Soc'y for Relief*, No. 07 Civ. 292, 2014 WL 3905742, at *16 (S.D.N.Y. Aug. 7, 2014) (Rule 9(b) protects defendants from "blunderbuss claims of fraud" wielded like a "club").

A. Relator's Proffered "False Claims" Are Neither Pled with Particularity Nor Representative

Relator's TAC falls far short of Rule 9(b)'s standard. His only attempt to plead with particularity ***any false claims*** comprises little more than two paragraphs alleging that a few physicians "received high volumes of" Acular LS® or Zymar® samples and prescribed "high

[18] The TAC alleges in passing that Allergan "falsely certified its compliance" with California Health and Safety Code Sections 119400 and 119402, which require drug companies to have a compliance program. TAC ¶ 254. But Relator neither links this allegedly false certification to any particular claims nor asserts that any such certification was material to any governmental health program. Thus, this theory, too, cannot survive *Escobar*. 136 S. Ct. at 1996 (emphasizing enforcement of the FCA's "rigorous materiality requirement").

volumes" of those drugs to Medicare patients. TAC ¶¶ 130–131. But those two paragraphs lack any detail about the allegedly false claims themselves, including the key details discussed below.

Third-Party Conduct and Records. A *qui tam* complaint does not satisfy Rule 9(b) if it neither identifies the third parties that a defendant allegedly caused to submit false claims nor details the third parties' conduct in the alleged scheme. *See United States ex rel. Osmose, Inc. v. Chem. Specialties, Inc.*, 994 F. Supp. 2d 353, 365 (W.D.N.Y. 2014) (where "the apparent theory underlying Relator['s] FCA cause of action depends heavily on the independent actions of various third parties," a lack of "specific allegations identifying those [third parties] . . . [leaves] the allegations . . . simply too tenuous"). Moreover, a plaintiff must identify the speaker of allegedly false statements to satisfy Rule 9(b). *Wood*, 2008 WL 2566728, at *5; *see also In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 265 (2d Cir. 1993) (holding that Rule 9(b) does not permit "pleading of fraud through completely unattributed statements").

Nowhere does Relator allege that Allergan submitted false claims to government health care programs. Instead, Relator contends that "Allergan's kickbacks caused ***pharmacies and others*** submitting claims to the Government to falsely certify compliance with applicable laws and regulations." TAC ¶ 133. But Relator fails to identify a single pharmacy allegedly involved in submitting a claim, *see id.* ¶¶ 130–131—let alone a single "false" certification submitted by such a pharmacy to a government health care program to secure reimbursement for a prescription. *Cf. id.* ¶¶ 226–227 (generalized allegations regarding the claims submission process).[19] Nor does Relator specify a single false record created by the unnamed third-party

[19] At best, Relator has alleged the contents of specific categories of claims forms, *see, e.g.*, TAC ¶¶ 82, 242, without alleging that a ***single one*** of the physicians named in the TAC—much less any of the pharmacies and contractors that Relator fails to name—actually submitted any such form. The heightened pleading requirements of Rule 9(b) require more. *See United States ex rel. Siegel v. Roche Diagnostics Corp.*, 988 F. Supp. 2d 341, 346 (E.D.N.Y. 2013) (dismissing under Rule 9(b) where relator did not plead "either a specific claim for payment that was submitted to the Government . . . or the specific details of an actual Medicaid/Medicare provider certification form signed by a particular provider"); *United States ex rel. Moore v. GlaxoSmithKline,*

entities mentioned in his overview of the Medicaid and Medicare reimbursement processes. *See id.* ¶¶ 225–237. As a result, Relator fails to plead critical details required by Rule 9(b).

Alleged Kickbacks. Relator makes only a feeble effort to connect the physicians named in paragraphs 130 and 131 of the TAC—and the "Medicare claims" from 2010 that he attributes to those physicians—to the alleged kickback scheme. According to Relator, that scheme involved four types of inducements: "free drugs" (i.e., samples), care kits, patient instruction sheets, and preprinted prescription pads. *See id.* ¶ 125. But Relator does not plausibly allege that Allergan's provision of a "high volume" of samples to the physicians named in paragraphs 130 and 131 violated the PDMA, let alone the AKS. *See id.* ¶¶ 130–131. To the contrary, he simply alleges that the physicians "received high volumes of" Acular LS® or Zymar® samples (a permissible practice, as discussed in Part III, *supra*) and "subsequently prescribe[d] high volumes" of those drugs, resulting in Medicare claims in 2010. *Id.* Yet, the TAC includes no allegations regarding the physicians' prescribing habits ***before*** they purportedly received samples from Allergan. Nor does Relator contend that the identified physicians received care kits, patient instruction sheets, or preprinted prescription pads.[20] Absent more detail, Rule 9(b) precludes this Court from presuming connections between the purported kickback scheme and the "sample" alleged claims.

Government Health Care Programs Other Than Medicare. In addition to Medicare, the TAC mentions several other government health care programs. *See id.* ¶ 101. Yet each of the TAC's "sample" claims relates to "Medicare Part D patients." *See id.* ¶¶ 130–131. Even if those alleged Medicare claims sufficed under Rule 9(b)—and, as explained in this section, they do not—Relator would still have to plead specific, representative examples of claims associated

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LLC, No. 06 Civ. 6047, 2013 WL 6085125, at *5 (E.D.N.Y. Oct. 18, 2013) (same).

[20] At most, Relator has vaguely alleged that certain practices and physicians received kits, instruction sheets, and pads. *See* TAC ¶¶ 159, 216. But Relator fails to sufficiently tie these physicians to any particular claims. As such, Relator has not pled with the requisite particularity any claims tied to those alleged inducements.

with other government health care programs to satisfy Rule 9(b). *See Mooney*, 2013 WL 1346022, at *6, *7–8 & n.6 ("Since plaintiff has failed to allege any specific claims relating to Medicaid, the Court finds that plaintiff has failed to satisfy the heightened pleading standard as to Medicaid claims . . . ."). Indeed, as Relator concedes, the government health care programs at issue involve different regulations and requirements. *See* TAC ¶ 79 (noting that the "Medicaid Provider Application varies from state to state"). Given these nuances, the alleged Medicare claims are not representative of claims to other government health care programs.[21]

B. Relator Does Not Plead a Multi-State, Multi-Year Scheme with Particularity

Even if this case is allowed to proceed, this Court should limit its scope—temporally and geographically—to any claims pled with particularity. Relator's cursory allegations focus on specific physicians from just five states, using sampling data from 2008 and 2009 and aggregate Medicare claims data from 2010. *See id.* ¶¶ 130–131. Further, Relator fails to plead details regarding care kits before 2005. *See id.* ¶ 146. Relator's conclusory, incomplete allegations are insufficient to plead adequately a nationwide scheme. *Hericks v. Lincare Inc.*, No. 07-387, 2014 WL 1225660, at *8 (E.D. Pa. Mar. 25, 2014) (nationwide allegations failed under Rule 9(b) because relator did not "plead[] actual knowledge of practices occurring in [defendant's] centers nationwide or for periods of time predating or postdating her employment").[22]

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[21] As if the above deficiencies were not enough, Relator also does not plead the ***claim amounts***, how much the government ***actually paid***, a single ***specific date*** on which any claim was submitted to the government, or any detail regarding the ***patients*** for whom the alleged prescriptions were written. Courts in this Circuit have dismissed cases where relators failed to plead this type of information. *See United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 265 (S.D.N.Y. 2014) (omitting the "total reimbursement amount" of "sample" claims strips pleading of the required specificity); *Mooney*, 2013 WL 1346022, at *4 & n.2 (patient privacy concerns did "not lessen the standard for compliance with Rule 9(b)"); *United States ex rel. Chapman v. Office of Children & Fam. Servs. of State of N.Y.*, No. 1:04-CV-1505, 2010 WL 610730, at *4 (N.D.N.Y. Feb. 16, 2010) (dismissing complaint in part because it alleged total overcharges resulting from a scheme, without providing "specific amounts" contributing to the totals), *aff'd*, 423 F. App'x 104 (2d Cir. 2011); *United States ex rel. Vallejo v. Investronica, Inc.*, 2 F. Supp. 2d 330, 337 (W.D.N.Y. 1998) (complaint was insufficient under Rule 9(b) in part because, even though relator pled two false statements that allegedly occurred in March 1990 and June 1990, he "failed to allege the date or dates on which these statements were made").

[22] *See also United States ex rel. West v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1222 (W.D.

VI. ALLERGAN PLC IS NOT SUBJECT TO THIS COURT'S JURISDICTION

Allergan plc is an Irish holding company that does not ***conduct any business operations in the United States*** and ***did not exist*** at the time of the events alleged in Relator's TAC. As such, this Court lacks both general and specific jurisdiction over Allergan plc, and this Court should dismiss Allergan plc pursuant to Federal Rule of Civil Procedure 12(b)(2).

A. Relator Cannot Establish General or Specific Jurisdiction over Allergan plc

Due process precludes the exercise of personal jurisdiction over a defendant that lacks sufficient "minimum contacts" with a forum. *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945).[23] Relator bears the *prima facie* burden of showing that Allergan plc is subject to jurisdiction in the United States by offering more than "conclusory" allegations, *SPV OSUS Ltd. v. UBS AG*, 114 F. Supp. 3d 161, 167 (S.D.N.Y. 2015), but he fails to do so.

General Jurisdiction. Absent "exceptional" circumstances where an entity's operations are so substantial as to render it "at home" in another forum, the entity is only subject to "the exercise of general jurisdiction" in its place of incorporation and principal place of business. *Daimler AG v. Bauman*, 134 S. Ct. 746, 761 (2014). As the Second Circuit has concluded, "even a company's engagement in a substantial, continuous, and systematic course of business is alone insufficient to render it at home in a forum." *Sonera Holding B.V. v. Cukurova Holding A.S.*, 750 F.3d 221, 226 (2d Cir. 2014) (per curiam) (alterations and quotation marks omitted) (quoting *Daimler*, 134 S. Ct. at 761); *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 627, 629 (2d Cir. 2016) (requiring a "truly 'exceptional'" showing that a forum is a "surrogate principal place of business" for an entity).

Wash. 2011) (holding that relators cannot "extrapolate a broader scheme" from the complaint's limited factual allegations); *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 723–24 (N.D. Tex. 2011) (dismissing state claims where the relator failed to allege facts specific to those states).

[23] "[T]he relevant inquiry is whether the defendants have minimum contacts with the United States as a whole." *United States ex rel. Thistlethwaite v. Dowty Woodville Polymer, Ltd.*, 976 F. Supp. 207, 210 (S.D.N.Y. 1997).

Allergan plc is incorporated and headquartered in Ireland, not the United States. TAC ¶¶ 24, 27; D'Arecca Decl. ¶ 3. And, despite Relator's conclusory allegation that "Allergan plc maintains substantial corporate, manufacturing and distribution offices and facilities in the United States," TAC ¶ 27, Allergan plc's contacts with the United States fall far short of even ***that*** level of activity, let alone an "exceptional" level that would render it "at home" in the United States for purposes of general jurisdiction. D'Arecca Decl. ¶¶ 3, 6, 9–10 (Allergan plc has ***never conducted business operations in the United States***, has no offices or facilities in the United States, and has no employees there other than certain U.S.-resident officers and directors.).

Even if Relator's allegations were true—and they are not—*SPV OSUS* demonstrates that Allergan plc lacks the requisite level of contact with the United States to permit this Court to exercise jurisdiction. There, this Court held that the plaintiff failed to show an "exceptional case" for jurisdiction over a defendant incorporated and headquartered in Switzerland, even though that entity had offices in the forum, "conduct[ed] substantial business" in the forum, and registered an agent in the forum. 114 F. Supp. 3d at 168.

Specific Jurisdiction. This Court lacks specific jurisdiction over Allergan plc because it has not purposefully directed any relevant activity at the United States and, even if it had, this litigation does not "arise out of or relate to" any such activity. *Gucci Am., Inc. v. Weixing Li*, 768 F.3d 122, 136 (2d Cir. 2014) (alterations omitted) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (requiring "the litigation [to have] result[ed] from alleged injuries that arise out of or relate to" activities "purposefully directed" at a forum)).

Allergan plc (which changed its name from Actavis plc in June 2015) ***was not even incorporated*** until May 16, 2013 and did not acquire Allergan, Inc. until March 2015, well ***after***

the activities alleged in the TAC purportedly occurred. TAC ¶ 26; D'Arecca Decl. ¶¶ 4–5. Nor has Allergan plc manufactured, distributed, marketed, promoted, or sold any pharmaceutical products in the United States, let alone those at issue in the TAC. *Id.* ¶ 10. Relator appears to acknowledge as much in his TAC, which focuses exclusively on ***Allergan, Inc.'s*** purported activities. *See, e.g.*, TAC ¶¶ 1, 3.

Again, *SPV OSUS* reveals the right result here. There, plaintiffs "fail[ed] to allege any meaningful connection whatsoever between defendants' conduct (much less their forum-directed conduct) and plaintiffs' injuries." 114 F. Supp. 3d at 170. Here, too, Relator's claims do not "arise out of or relate to" Allergan plc's contacts with the United States. Thus, this Court cannot properly exercise specific jurisdiction over Allergan plc.[24]

B. Allergan plc Is Not Subject to Personal Jurisdiction Through Its Subsidiaries

Relator further alleges that Allergan plc "control[s]" Allergan, Inc. and that the two entities "function as one, integrated entity." TAC ¶ 29. According to Relator, Allergan plc also assumed Allergan Inc.'s liabilities. *Id.* ¶ 24. But even if these assertions were accurate (and they are not), they would not suffice to provide this Court with personal jurisdiction:

- ***First***, contrary to Relator's allegations, Allergan plc is merely a holding company that maintains a separate formal corporate existence from Allergan Inc., which operates separately and independently of Allergan plc, conducts its own day-to-day operations, and authorizes and implements its own business policies. D'Arecca Decl. ¶¶ 6–8.

- ***Second***, a parent company's "considerable degree of control over [a] subsidiary corporation . . . is not enough to subject the parent" to jurisdiction. *Volkswagenwerk Aktiengesellschaft v. Beech Aircraft Corp.*, 751 F.2d 117, 120 (2d Cir. 1984). Rather, for *Allergan Inc.'s* activities in the United States to form the basis for jurisdiction over *Allergan plc*, it must have "disregard[ed] . . . the separate corporate existence of the subsidiary," *id.*, such that the two are "alter ego[s]," *Sonera Holding B.V.*, 750 F.3d at 225 (after *Daimler*, the relevant analysis is "whether [an] affiliate is so dominated by the defendant as to be its

[24] Nor would "the assertion of personal jurisdiction" "comport with fair play and substantial justice." *Gucci*, 768 F.3d at 136 (quoting *Burger King*, 471 U.S. at 476).

alter ego"). "[T]o plead adequately that one entity is the alter ego of another for jurisdictional purposes, the plaintiff must plead that the allegedly controlled entity was a shell for the allegedly controlling party." *Noval Williams Films LLC v. Branca*, 128 F. Supp. 3d 781, 787 (S.D.N.Y. 2015). This, Relator fails to do.

- ***Third***, contrary to the allegations in the TAC, Allergan plc did not assume any potential liability that Allergan, Inc. may incur in connection with this matter as part of the merger agreement that the TAC references. D'Arecca Decl. ¶ 4.

Thus, the Court cannot exercise jurisdiction based on the contacts of Allergan plc's subsidiaries with the United States.[25]

VII. APPLICABLE STATUTES OF LIMITATION PRECLUDE SIGNIFICANT PORTIONS OF RELATOR'S CLAIMS

As discussed in Part I, *supra*, this case must be dismissed in its entirety under the first-to-file bar. But even if this Court does not, as a procedural matter, dismiss on first-to-file grounds (which would require Relator to re-file if he wishes to salvage his suit), the TAC is the operative complaint for purposes of calculating the six-year statute of limitations period under 31 U.S.C. § 3731(b)(1) because the prior complaints violated the first-to-file bar. *See United States v. Cephalon, Inc.*, No. 08-287, 2016 WL 398014, at *7 (E.D. Pa. Feb. 2, 2016) ("As . . . the first amended complaint can[not] survive the first-to-file bar, the second amended complaint is the operative complaint for measuring the applicable six-year statute of limitations . . . .").[26] Thus, Relator's FCA claims (and twenty-one of his state-law claims that also are subject to six-year statutes of limitation[27]) must be dismissed to the extent they relate to alleged false claims

[25] The TAC's sparse, half-hearted allegations regarding Anda, Inc. do not provide a basis for this Court to exercise jurisdiction. Relator does not allege Allergan plc exercised ***any*** control over Anda, Inc. (let alone that it was an alter ego). And, as in the case of Allergan, Inc., even if Anda were subject to jurisdiction, Relator "cannot rely on the fact that [the holding company] is a parent of operating companies over whom this Court could properly exercise jurisdiction as a basis for jurisdiction over [the holding company]." *In re Aluminum Warehousing Antitrust Litig.*, 90 F. Supp. 3d 219, 232 (S.D.N.Y. 2015).

[26] The *Lampkin* action, which was based on the same material facts alleged here, was not dismissed as to Allergan until December 14, 2012. *See* RJN Ex. 2, 5. Relator filed his FAC on August 19, 2010, ECF No. 63, and the SAC on March 15, 2012, ECF No. 27, before the *Lampkin* action was dismissed. Accordingly, the jurisdictional defect was not cured under the approach adopted in *Cephalon* until Relator filed the TAC on May 23, 2016.

[27] Cal. Gov't Code § 12654(a); Colo. Rev. Stat. § 25.5-4-307(1)(a); Conn. Gen. Stat. § 17b-3011; Del. Code. Ann. tit. 6, § 1209(a)(1); D.C. Code § 2-381.05(a)(1); Fla. Stat. § 68.089(1)(a); Ga. Code Ann. § 23-3-123(a); 740 Ill.

submitted before May 23, 2010, the date six years before he filed the TAC. *See id.*; *see also United States ex rel. Bergman v. Abbot Labs.*, 995 F. Supp. 2d 357, 387 (E.D. Pa. 2014) (dismissing state claims "limited by this six-year statute of limitations").[28]

VIII. RELATOR'S STATE CLAIMS SUFFER FROM SEVERAL LEGAL DEFECTS

Relator's state-law claims must be dismissed in whole or in part for several other reasons. ***First***, Relator's Wisconsin claim must be dismissed because that state's legislature repealed its false claims act in July 2015. *See* 2015 Wisconsin Act 55 § 945n (July 12, 2015). ***Second***, where, as here (*see* ECF No. 25), New Mexico "declines to take over the action," a relator may proceed only if the state determines "that there is substantial evidence" of a violation. N.M. Stat. Ann. § 27-14-7(E)(2). Relator has failed to allege that New Mexico made such a determination and thus cannot proceed with his claim. *See United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 603–04 (E.D. Pa. 2012). ***Third***, Delaware and Texas false claims provisions in effect during a portion of the relevant period precluded actions if the state declined to intervene (or to issue a written determination, for Delaware). Del. Code Ann. tit. 6, § 1203(b)(2)-(4) (2005); Tex. Hum. Res. Code § 36.104(b) (2008). Delaware and Texas have since removed these requirements, but the claims must be dismissed insofar as they are based on conduct "preceding those statutes' [amendments'] effective dates." *Streck*, 894 F. Supp. 2d at 603–05 (dismissing Delaware and Texas counts to the extent they were based on conduct predating the amendments);

Comp. Stat. 175/5(b)(1); Ind. Code § 5-11-5.5-9(b)(1); La. Rev. Stat. Ann. § 46:439.1(B); Mass. Gen. Laws ch. 12, § 5K(1); Mich. Comp. Laws § 400.614(1)(a); Minn. Stat. Ann. § 15C.11(a); Mont. Code § 17-8-404; Nev. Rev. Stat. § 357.170(1); N.C. Gen. Stat. § 1-615(a); N.J. Stat. Ann. § 2A:32C-11; Okla. Stat. tit. 63, § 5053.6(B)(1); R.I. Gen. Laws § 9-1.1-5(b)(1); Tenn. Code Ann. § 71-5-184(b)(1); Va. Code Ann. § 8.01-216.9.

[28] Even if the Court determines that the first-to-file bar does not apply, it should still dismiss Relator's claims to the extent they relate to alleged false claims submitted before July 26, 2004, i.e., six years before the original complaint. *See* 31 U.S.C. § 3731(b)(1); *see also United States ex rel. Capella v. Norden Sys., Inc.*, No. 3:94-cv-2063, 2000 WL 1336487, at *12 (D. Conn. Aug. 24, 2000). If not dismissed outright, the New Mexico count should be dismissed as to conduct occurring before March 21, 2012, under the applicable four-year statute of limitations. *See* N.M. Stat. Ann. §§ 27-14-13, 37-1-4.

United States ex rel. Bergman v. Abbot Labs., No. 09-4264, 2014 WL 348583, at *17–19 (E.D. Pa. Jan. 30, 2014) (same). ***Fourth***, ten of Relator's claims should be dismissed because they depend, in part, on improper retroactive application of state law.[29] Relator alleges conduct that purportedly took place between, at most, 2003 and 2011. *See* TAC ¶¶ 2, 245, 252. Yet ten state laws that he invokes were not enacted until well into that time period, and those laws expressly forbid (or are silent as to) retroactivity. This Court should therefore dismiss those claims to the extent Relator alleges conduct occurring before each statute's effective date.[30]

IX. RELATOR FAILS TO STATE A RETALIATION CLAIM

Relator alleges that Allergan terminated him (in violation of 31 U.S.C. § 3730(h)) after he reported internally "specific information regarding sampling directives and activities that he believed . . . were in violation of Allergan's policies and Federal law." TAC ¶ 269. To state such

[29] *See Bergman*, 2014 WL 348583, at *24–25 (declining to retroactively apply Indiana, Montana, New Jersey, Oklahoma, Rhode Island, and Virginia statutes); *Streck*, 894 F. Supp. 2d at 603–05 (Connecticut, Georgia, Indiana, Montana, Oklahoma, and Rhode Island); *United States ex rel. Bogart v. King Pharm.*, 410 F. Supp. 2d 404, 406–08 (E.D. Pa. 2006) (New Mexico), *aff'd*, 493 F.3d 323 (3d Cir. 2007); *United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 520–21 (S.D. Tex. 2011) (Connecticut, Georgia, Indiana, Minnesota, Montana, New Jersey, Oklahoma, Rhode Island, and Virginia).

[30] **Connecticut** False Claims Act, Conn. Gen. Stat. § 17b-301a (2009) *et seq.* (effective Oct. 5, 2009); *see* Conn. Gen. Stat. § 55-3 ("No provision of the general statutes . . . which imposes any new obligation on any person or corporation, shall be construed to have a retrospective effect."); **Georgia** False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq*. (effective May 24, 2007); *see Fowler Props., Inc. v. Dowland*, 646 S.E.2d 197, 200 (Ga. 2007) ("[L]egislation which affects substantive rights may only operative prospectively."); **Indiana** False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.* (effective July 1, 2005); *see State v. Pelley*, 828 N.E.2d 915, 919 (Ind. 2005) ("Statutes are to be given prospective effect only, unless the legislature unequivocally and unambiguously intended retrospective effect as well."); **Minnesota** False Claims Act, Minn. Stat. Ann. § 15C.01 *et seq.* (effective July 1, 2010); Minn. Stat. Ann. § 645.21 ("No law shall be construed to be retroactive unless clearly and manifestly so intended . . . ."); **Montana** False Claims Act, Mont. Code Ann. § 17-8-401 (2005) *et seq.* (effective May 1, 2005); 2005 Mont. Laws Ch. 465 § 14 (rendering Montana FCA effective on May 1, 2005); *see State v. Hamilton*, 164 P.3d 884, 886 (Mont. 2007) (same); **New Jersey** False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.* (effective Mar. 13, 2008); *see Oberhand v. Dir., Div. of Taxation*, 940 A.2d 1202, 1209 (N.J. 2008) (there is a general rule of prospective application unless the legislature expresses a contrary intent); **New Mexico** False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* (effective May 19, 2004); *see Howell v. Heim*, 882 P.2d 541, 547 (N.M. 1994) (a presumption against retroactive application applies "absent a clear intention to the contrary"); **Oklahoma** Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.* (effective Nov. 1, 2007); *see CAN Ins. Co. v. Ellis*, 148 P.3d 874, 877 (Okla. 2006) (disapproving retroactive application of statutes); **Rhode Island** False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.* (effective July 1, 2007); *see Pion v. Bess Eaton Donuts Flour Co.*, 637 A.2d 367, 371 (R.I. 1994) (statutes operate prospectively absent clear legislative intention to the contrary); **Virginia** Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq.* (effective Jan. 1, 2003); *see Adams v. Alliant Techsystems, Inc.*, 544 S.E.2d 354, 356 (Va. 2001) (statutes operate prospectively "unless a contrary intent is manifest"). *See also* Appendix I.

a claim, Relator must plead that (1) he engaged in protected activity, (2) Allergan was aware of that activity, and (3) Allergan retaliated against him "because of" that activity. *See, e.g.*, *Mooney*, 2013 WL 1346022, at *8. Because Relator fails to allege adequately that he engaged in protected activity, his claim should be dismissed under Rules 8 and 12(b)(6).

An employee's reports regarding "'nothing more than his employer's non-compliance with . . . regulations' is not enough to support a whistleblower claim." *United States ex rel. Hoyte v. Am. Nat'l Red Cross*, 518 F.3d 61, 67 (D.C. Cir. 2008) (quoting *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 740 (D.C. Cir. 1998) (applying prior version of 31 U.S.C. § 3730(h)). Yet, here, Relator alleges that he reported on "his concerns about the illegal sampling and kickback scheme" and specifically about "sampling directives and activities." TAC ¶¶ 268, 269. Even assuming the truth of the TAC's allegations, Relator's internal reports to Allergan personnel focused on purported violations of the PDMA—i.e., mere acts of regulatory non-compliance that would not give rise to FCA liability and thus cannot support a retaliation claim. *See Hoyte*, 518 F.3d at 67 (distinguishing cases involving "classic false claim[s]," such as "attempting to defraud the Government of money[,]" which "could not have been mistaken for a complaint about mere regulatory compliance") (internal quotation marks and citation omitted).[31]

CONCLUSION

For the reasons set forth above, Allergan respectfully requests that this Court dismiss Relator's TAC with prejudice.

[31] Regardless, Relator cannot plausibly plead that he believed in good faith that providing samples to persuade physicians to write prescriptions amounts to a kickback given that the PDMA expressly authorizes that activity. *Cf. United States ex rel. Sasaki v. N.Y. Univ. Med. Ctr.*, No. 05 Civ. 6163, 2012 WL 220219, at *12 (S.D.N.Y. Jan. 25, 2012) (a relator must have a "good faith basis" or "objectively reasonable basis" for his belief that he was reporting on issues that would support a viable FCA suit).

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Respectfully submitted,

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I hereby certify that on August 4, 2016, true and correct copies of the foregoing pleading have been served on the following in the manner listed below.

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